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| EXAMINER | |
|---|---|
| MACFARLANE, STACEY NEE | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/542,435 | ROTHSTEIN ET AL. | |
| | Examiner | Art Unit | |
| | STACEY MACFARLANE | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1,5,6,8,11,12,18 and 20-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,7,9,10,13-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Claims 9, 13-14, and 19 have been amended as requested in the amendment filed on December 10, 2007. Following the amendment, claims 1-44 are pending in the instant application.

Claims 1, 5, 6, 8, 11, 12, 18 and 20-44 withdrawn without traverse from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions in the Paper filed April 17, 2007, there being no allowable generic or linking claim.

Claims 2-4, 7, 9-10, 13-17 and 19 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on December 10, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record in the Office Action mailed June 13, 2007.

On pages 9-10 of Remarks filed December 10, 2007 Applicants traverse the rejection on the grounds that not every claimed embodiment need be operable, for example, where a compound binds GTRAP3-18 and is not a glycosylation modulator, Applicant asserts that the specification has provided adequate guidance in the form of screening assays to identify compounds which modulate GTRAP3-18 expression or activity such that it would not be undue experimentation to test a compound that bids GTRAP3-18 as a treatment for one of the disclosed diseases. This argument has been fully considered but is not found persuasive to overcome the rejection for the following reasons.

With respect to claim breadth, the standard under 35 U.S.C. §112, first paragraph, entails the determination of what the claims recite and what the claims mean as a whole. In addition, when analyzing the scope of enablement, the claims are analyzed with respect to the teachings of the specification and are to be given their broadest reasonable interpretation that is consistent with the specification. See MPEP 2111 [R-1], which states: "During patent examination, the pending claims must be "given *>their< broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 51 (CCPA 1969)".

As such, the broadest reasonable interpretation of the claimed method wherein the compound is capable of treating any neurological or psychiatric glycosylation association disorder including genetically inherited disorders, infections, or trauma. Thus, the claims encompass treatment of an unreasonable number of pathologically distinct conditions and disorders, many of which have no nexus or association with levels of glycosylation. A skilled artisan would not know how to evaluate these diseases based solely on the identification of a compound that modulates (increases or decreases) the expression or activity of GTRAP3-18. Furthermore, the standard of an enabling disclosure is not the ability to make and test if the invention worked but one of the ability to make and use with a reasonable expectation of success. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech, Inc, v. Novo Nordisk*, 42 USPQ 2d 1001, (CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the

specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one cannot follow the guidance presented therein and practice the claimed method without first making a substantial inventive contribution. In the instant case, one of ordinary skill in the art would have to first identify diseases for which increased or decreased GTRAP3-18 expression and/or activity were correlated with etiology or pathological development of disease, identify compounds that modulate (increase or decrease) GTRAP3-18 expression and/or activity, and then bridge the gap between laboratory identification and clinical efficacy by demonstrating that administration of said compound treated the disease with a reasonable expectation of success. Such experimentation would be considered undue experimentation within the art. Thus, for reasons of record in the previous Office Action and for reasons above, the instant rejection is maintained.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 2, 4, 7, 9-10, 13 and newly amended claim 19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. Nature 410: 84-88, published March 1, 2001 as applied to claims 2, 4, 7, 9-10 and 13 in the Office Action dated June 13, 2007..

On pages 12-13 of Remarks filed December 10, 2007, Applicants traverse the rejection on the grounds that the Lin et al reference fails to teach each and every element of the claimed invention because the claims expressly recite "wherein a compound that can modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide or the activity of a GTRAP3-18 polypeptide is identified as a compound capable of modulating cellular glycosylation". Applicants assert that the Lin et al. reference fails to correlate GTRAP3-18 activity or expression to cellular glycosylation or identify such a modulator. While this argument has been fully considered it is not found persuasive to overcome the rejection for the following reasons.

The limitation recited within the claim is the result step of the active steps of the method, whereby the compound is identified. The Lin prior art teaches each of the active steps of the claimed method, contacting a neuronal cell with a test compound (antisense oligomers) and assaying the ability of the test compound to modulate the expression GTRAP3-18 protein expression and activity (Figure 3d) as determined by glutamate transport, EAAC1, activity. Thus, the Lin reference teaches each element of the claimed method and the reference fully anticipates instant claims 2, 4, 7, 9-10, 13 and 19 and the rejection is maintained.

7. Claims 2, 4, 7, 9, 13 and 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6808893 ('893 Patent) for reasons of record in the Office Action mailed June 13, 2007.

On page 13 of the Remarks filed December 10, 2007, Applicants traverse the rejection on the grounds that the '893 Patent fails to teach each and every element of the claimed invention because the claims expressly recite "wherein a compound that can modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide or the activity of a GTRAP3-18 polypeptide is identified as a compound capable of modulating cellular glycosylation", and Applicants assert that the '893 Patent fails to correlate GTRAP3-18 activity or expression to cellular glycosylation or identify such a modulator. While this argument has been fully considered it is not found persuasive to overcome the rejection for the following reasons.

As stated above, the limitation recited within the claim is the result step of the active steps whereby the compound is identified. The '893 Patent teaches neuronal cells contacted with antisense oligomers (Figure 8A-C), upon assay, demonstrate reduced GTRAP3-18 protein expression and activity and cells contacted with retinoic acid increase GTAP3-18 expression (¶ 219). Therefore, the prior art patent teaches teaches each element of the claimed method and the reference fully anticipates instant claims 2, 4, 7, 9-10, 13 and 19 and the rejection is maintained.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. as applied to claims 2, 4, 7, 9-10 and 13 above, and further in view of Hirabayashi and Kasai, Journal of Chromatography B 771: 67-87, published May 5, 2002, for reasons of record in the Office Action mailed June 13, 2007.

On pages 13-14 of Remarks filed December 10, 2007, Applicants traverse this rejection on the grounds that Under KSR three criteria are considered: (1) some suggestion or motivation to modify a reference or to combine teachings of multiple references still has to be shown; (2) the combination has to suggest a reasonable expectation of success; and (3) the prior art reference or combination has to teach or suggest all of the recited claim limitations. Applicants assert that these criteria are not evident within the references or combination thereof and therefore a *prima facie* case of obviousness has not been established. While this argument has been fully considered it is not found persuasive for the following reasons.

The *KSR* decision forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, USPQ2d, slip op at 20 (Bd. Pat. Appl. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396). Rather, In *KSR International Co. v.*

*Teleflex, Inc.*, the Supreme Court has stated that combining prior art elements according to known methods to yield predictable results is *prima facie* obvious if the following rationale can be applied:

> (1) the prior art includes each element claimed though not necessarily in the same reference.
>
> (2) it was within the technical grasp of one of ordinary skill in the art to combine the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.
>
> (3) one of ordinary skill in the art would have recognized that the results of such combination were predictable.

*(KSR International Co. v. Teleflex, Inc.* 127 S. Ct. 1727, 82 USPQ2d 1385, Supreme Court, April 30, 2007).

One of ordinary skill in the art would recognize the use of methods to detect the levels of glycosylation of glycosylation target proteins, as taught by Hirabayashi and Kasai, in combination with the method comprising contacting a cell expressing GTRAP3-18 with a test compound and assaying the ability of the test compound to modulate the expression and/or activity of GTRAP3-18, as taught by Lin et al. A skilled artisan would be motivated to combine the prior art elements because combination would result in identification of a broader range of compounds capable of binding GTRAP3-18 and potentially modulating GTRAP3-18 expression and/or activity. Based on the guidance and direction within the prior art, such combination would have been well within the technical grasp of a skilled artisan. Since each of the elements in combination are merely performing the same function as they did separately, then one of ordinary skill in the art would have been able to predictably combine the elements of

each method with a reasonable expectation of success. Therefore, the invention as a whole is *prima facie obvious*, if not actually anticipated by the reference and the rejection of record in the previous Office Action is maintained.

***Conclusion***

10. No Claim is allowed.

11. This application contains claims drawn to an invention nonelected without traverse in Paper filed on April 17, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

12. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT. F 6 am to 3 pm, T & R 5:30 am - 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

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